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Glossary of Risk Assessment Related Terms (N - Z)

Neoplasm: An abnormal growth of tissue which may be benign or malignant.

No-Observed-Adverse-Effect Level (NOAEL): An highest exposure level at whic are no statistically or biologically significant increases in the frequency or severity adverse effect between the exposed population and its appropriate control; some may be produced at this level, but they are not considered adverse, nor precursor adverse effects.

No-Observed-Effect Level (NOEL): An exposure level at which there are no stati or biologically significant increases in the frequency or severity of any effect betwe exposed population and its appropriate control.

Non-linear dose response: A pattern of frequency or severity of biological respo does not vary proportionately with the amount of dose of an agent. When mode of information indicates that responses may not follow a linear pattern below the dos of the observed data, non-linear methods for determining risk at low dose may be

Odds Ratio (OR): A relative measure of the difference in exposure between the d (cases) and not diseased (controls) individuals in a case-control study. The OR is interpreted similarly to the relative risk.

Oncogenic: Resulting from a gene which can induce neoplastic transformations i cell in which it occurs or into which it is introduced.

One hit Model: A dose-response model based on a mechanistic argument that th response after a target site has been hit by a single biologically effective unit of dc within a given time period. The form of the model, a special case of the gamma, multistage, and Weibull models, is given by:

$$P(d) = 1 - \exp(-Id)$$

where P(d) = probability of cancer from lifetime continuous exposure at dose rate

I = fitted dose coefficient.

Organoleptic: Affecting or involving a sense organ such as that of taste, smell, o

Physiologically Based Pharmacokinetic (PBPK) Model: Physiologically based compartmental model used to characterize pharmacokinetic behavior of a chemic Available data on blood flow rates, and metabolic and other processes which the undergoes within each compartment are used to construct a mass-balance framev the PBPK model.

Point of Departure: The dose-response point that marks the beginning of a low-d

extrapolation. This point is most often the upper bound on an observed incidence estimated incidence from a dose-response model.

ppb: A unit of measure expressed as parts per billion. Equivalent to 1 x 10E-9.

ppm: A unit of measure expressed as parts per million. Equivalent to 1 x 10E-6.

Prevalence: The proportion of disease cases that exist within a population at a sp point in time, relative to the number of individuals within that population at the san in time.

Probit Model: A dose-response model of the form:

$$P(d) = g + ((1 - g) \times 1)/(\text{square root of } 2 \times \text{pi}) \times$$

$$\{\text{integral from minus infinity to } a + bd \text{ of } [\exp-(y^{**}2)/2]dy\}$$

where P(d) = the probability that an individual selected at random will respond at assuming a normal distribution of tolerances;

a, b = fitted parameters; and

g = background response rate.

Promoter: An agent that is not carcinogenic itself, but when administered after an of carcinogenesis, stimulates the clonal expansion of the initiated cell to produce a neoplasm.

Proportionate Mortality Ratio (PMR): The proportion of deaths due to the diseas interest in the exposed population divided by the proportion of deaths due to the d of interest in the unexposed or reference population. It is frequently converted to a by multiplying the ratio by 100.

Prospective Study: See cohort study.

Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limit the data used. Generally used in EPA's noncancer health assessments.

Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects dur lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncer factors generally applied to reflect limitations of the data used. Generally used in E noncancer health assessments.

Regional Deposited Dose (RDD): The deposited dose of particles calculated for respiratory tract region of interest (r) as related to an observed toxicity. For respira effects of particles, the deposited dose is adjusted for ventilatory volumes and the area of the respiratory region effected (mg/min-sq. cm). For extra respiratory effec particles, the deposited dose in the total respiratory system is adjusted for ventilat volumes and body weight (mg/min-kg).

Regional Deposited Dose Ratio (RDDR): The ratio of the regional deposited dos calculated for a given exposure in the animal species of interest to the regional de dose of the same exposure in a human. This ratio is used to adjust the exposure e level for interspecies dosimetric differences to derive a human equivalent concent for particles.

Regional Gas Dose: The gas dose calculated for the region of interest as related observed effect for respiratory effects. The deposited dose is adjusted for ventilat volumes and the surface area of the respiratory region effected (mg/min-sq.cm).

Regional Gas Dose Ratio (RGDR): The ratio of the regional gas dose calculated given exposure in the animal species of interest to the regional gas dose of the sa exposure in humans. This ratio is used to adjust the exposure effect level for inter dosimetric differences to derive a human equivalent concentration for gases with respiratory effects.

Relative Risk (or Risk Ratio (RR)): The relative measure of the difference in risk between the exposed and unexposed populations in a cohort study. The relative ri defined as the rate of disease among the exposed divided by the rate of the disea among the unexposed. A relative risk of 2 means that the exposed group has twic disease risk as the unexposed group.

Reserve Volume: The volume of air remaining in the lungs after a maximal expir

Residual Volume (RV): The lung volume after maximal expiration (TLC - VC).

Risk (in the context of human health): The probability of injury, disease, or dea exposure to a chemical agent or a mixture of chemicals. In quantitative terms, risk expressed in values ranging from zero (representing the certainty that harm will nc to one (representing the certainty that harm will occur). The following are example risk is expressed within IRIS: E-4 or 10-4 = a risk of 1/10,000; E-5 or 10-5 = 1/100 6 or 10-6 = 1/1,000,000. Similarly, 1.3 E-3 or 1.3 x 10-3 = a risk of 1.3/1,000=1/77 or 8 x 10-3 = a risk of 1/125 and 1.2 E-5 or 1.2 x 10-5 = a risk of 1/83,000.

Risk Assessment (in the context of human health): The determination of poter adverse health effects from exposure to chemicals, including both quantitative an qualitative expressions of risk. The process of risk assessment involves four majo hazard identification, dose-response assessment, exposure assessment, and risk characterization.

Risk Management (in the context of human health): A decision making proces accounts for political, social, economic and engineering implications together with related information in order to develop, analyze and compare management option select the appropriate managerial response to a potential chronic health hazard.

Short-Term Exposure: Multiple or continuous exposure to an agent for a short pe time, usually one week.

Sigma g: Geometric standard deviation. (See Mass Median Aerodynamic Diamet

Slope Factor: An upper bound, approximating a 95% confidence limit, on the incr cancer risk from a lifetime exposure to an agent. This estimate, usually expressed of proportion (of a population) affected per mg/kg/day, is generally reserved for us low-dose region of the dose-response relationship, that is, for exposures correspor risks less than 1 in 100.

Standardized Mortality Ratio (SMR): This is the relative measure of the differen risk between the exposed and unexposed populations in a cohort study. The SMR similar to the relative risk in both definition and interpretation. This measure is usu standardized to control for any differences in age, sex, and/or race between the e and reference populations. It is frequently converted to a percent by multiplying th by 100.

Statistical Significance: The probability that a result likely to be due to chance al convention, a difference between two groups is usually considered statistically sig if chance could explain it only 5% of the time or less. Study design considerations influence the a priori choice of a different statistical significance level.

Subchronic Exposure: Exposure to a substance spanning approximately 10% of lifetime of an organism.

Subchronic Study: A toxicity study designed to measure effects from subchronic exposure to a chemical.

Sufficient Evidence: A term used in evaluating study data for the classification o carcinogen under the 1986 U.S. EPA guidelines for carcinogen risk assessment. T classification indicates that there is a causal relationship between the agent or age human cancer.

Superfund: Federal authority, established by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) in 1980, to respond directly releases or threatened releases of hazardous substances that may endanger healt welfare.

Supporting Studies: Studies that contain information useful for providing insight support for conclusions.

Systemic Effects or Systemic Toxicity: Toxic effects as a result of absorption a distribution of a toxicant to a site distant from its entry point, at which point effects produced. Not all chemicals that produce systemic effects cause the same degree toxicity in all organs.

Target Organ: The biological organ(s) most adversely effected by exposure to a substance.

Teratogenic: Structural developmental defects due to exposure to a chemical ag during formation of individual organs.

Threshold: The dose or exposure below which no deleterious effect is expected t

Tidal Volume (VT): The volume of air inhaled/exhaled during normal breathing.

Total Lung Volume (TLV): The lung volume at maximal inspiration.

Toxicity: The degree to which a chemical substance elicits a deleterious or adver upon the biological system of an organism exposed to the substance over a desig time period.

Toxicology: The study of harmful interactions between chemicals and biological

Toxic Substance: A chemical substance or agent which may cause an adverse e effects to biological systems.

Tumor: An abnormal, uncontrolled growth of cells. Synonym: neoplasm.

Tumor Progression: Under the Armitage-Doll multistage theory of cancer develo the transition of a cell line between the stages which lead to cancer.

Threshold Limit Value (TLV): Recommended guidelines for occupational exposu airborne contaminants published by the American Conference of Governmental In Hygienists (ACGIH). TLVs represent the average concentration in mg/m3 for an 8- workday and a 40-hour work week to which nearly all workers may be repeatedly e day after day, without adverse effect.

Uncertainty Factor (UF): One of several, generally 10-fold factors, used in opera deriving the RfD and RfC from experimental data. UFs are intended to account fo variation in sensitivity among the members of the human population, i.e., interhun intraspecies variability; (2) the uncertainty in extrapolating animal data to humans interspecies variability; (3) the uncertainty in extrapolating from data obtained in a with less-than-lifetime exposure to lifetime exposure, i.e., extrapolating from subcl chronic exposure; (4) the uncertainty in extrapolating from a LOAEL rather than fr NOAEL; and (5) the uncertainty associated with extrapolation from animal data wh data base is incomplete.

Unit Risk: The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 μg/L in water, or 1 ug/m3 The interpretation of unit risk would be as follows: if unit risk = 1.5 x 10-6 ug/L, 1.5 tumors are expected to develop per 1,000,000 people if exposed daily for a lifetim ug of the chemical in 1 liter of drinking water.

Upper bound: An plausible upper limit to the true value of a quantity. This is usu true statistical confidence limit.

Vital Capacity (VC): The maximum volume that can be exhaled in a single breath RC).

Weibull Model: A dose-response model of the form:

$$P(d) = g + (1 - g)(1 - \exp -b[d ** a])$$

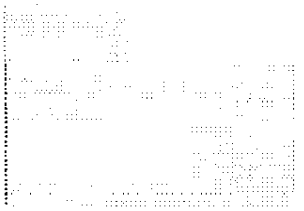
where P(d) = the probability of a tumor (or other response) from lifetime, contin exposure at dose d until age t (when tumor is fatal);

a = fitted dose parameter (sometimes called "Weibull" parameter);

b = fitted dose parameter;

g = background response rate.

Weight-of-Evidence (WOE) for Carcinogenicity: A system used by the U.S. EP characterizing the extent to which the available data support the hypothesis that a causes cancer in humans. Under EPA's 1986 risk assessment guidelines, the WO described by categories "A through E", Group A for known human carcinogens thr Group E for agents with evidence of noncarcinogenicity. The approach outlined in proposed guidelines for carcinogen risk assessment (1996) considers all scientific



information in determining whether and under what conditions an agent may cause in humans, and provides a narrative approach to characterize carcinogenicity rath categories.